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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,038	03/24/2000	Scott J. Wolf	7883.0004-02	2278

22852 7590 07/29/2005

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WASHINGTON, DC 20001-4413

EXAMINER
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BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/534,038

Applicant(s)

WOLF ET AL.

Examiner

Patricia M. Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15, 16 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15, 16 and 18-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/11/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/11/2005 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 15, 16, & 18-29 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 15, 16, 18-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Rapacki et al. (6,651,670). Rapacki discloses a method for delivering a conduit into the wall of the heart between a coronary artery and a heart chamber. Rapacki teaches that a needle is used to form an opening (i.e. channel) through heart tissue starting from the coronary artery into a heart chamber, namely the left ventricle. Since one is starting the lumen through the coronary artery, it is inherent that the device would pass first through the anterior and then through the posterior wall of the vessel and through the heart wall. Rapacki further teaches that the conduit is an expandable member (i.e. a stent) that is implanted using a support member that is a tube (i.e. a catheter system). With respect to the recitation in claim 29 that the implant does not extend substantially along an axial direction of the vessel, Rapacki shows the implant extending within the passageway offset from the vessel's axis in figures. Rapacki teaches that upon removing the support member, the conduit then expands. Thus, the limitation of radially expansion of the implant in the passageway is met. With respect to claims 21-24, Rapacki further teaches that the conduits may be used to deliver angiogenic growth factors.

Claims 15, 18-20, & 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Foley (2001/0025643). Foley discloses a method for delivering a conduit device to provide transmyocardial blood flow from the heart to the arterial vascular system, namely between a coronary artery and a heart chamber. Foley teaches that a

needle device is used to form a port (i.e. channel) through heart tissue starting from the coronary artery into a heart chamber, namely the left ventricle. Since one is starting the lumen through the coronary artery, it is inherent that the device would pass first through the anterior and then through the posterior wall of the vessel and through the heart wall. See figure 4. Foley further teaches that the conduit is a device that includes expandable projections (i.e. a stent) that are folded flat during delivery with the conduit and expand to an outwardly position after delivery using a catheter. With respect to the recitation in claim 29 that the implant does not extend substantially along an axial direction of the vessel, Foley shows the implant extending within the passageway perpendicular or offset from the vessel's axis in figures. Foley further teaches that the conduit may have biocompatible coatings disposed thereon.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (2001/0025643) in view of Evans et al. (5,980,548). Foley disclose the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the conduit's coating is a substance for delivery to the heart wall, wherein the substance is for one of generating, stimulating, and enhancing blood vessel

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formation, and wherein the substance is chosen from angiogenesis factors and nucleic acid instructions for angiogenesis factors.

Evans et al. disclose inserts for deployment into the heart wall and where the inserts may be hollow, tubular members that are equivalent to a stent or implant, and the inserts can be coated with or contain growth factors, or a material that will provide vasculature or angiogenesis in the heart wall (col. 14, lines 15-20 & col. 16, lines 10-31). At the time of the invention, it would have been an obvious design choice to modify the conduit of Foley by substituting the bio-compatible coating with a coating that contains growth factors or a material that will provide vasculature or angiogenesis in the heart wall as taught by Evans et al. to provide new growth of vessels and provide a lasting therapeutic effect, since substitution of parts which provide the same function would be within the level of ordinary skill in the art.

### ***Double Patenting***

Claims 15, 18, 20, & 24-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52-56, 60, 109, & 116-119 of copending Application No. 10/681,323 (Pub 2004/0147869). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a method for placing a conduit within the heart wall to provide blood flow between an artery and the heart chamber, and the instant application claims recite steps that are a broader recitation than those of the conflicting application. The claims match up as follows:

<u>Instant Application Claim No.</u>	<u>Application 10/681323 Claim No.</u>
15	54/53/52
15	55/56/52
15	117/116/52
15	119/118/60
18/15	60
20/15	109/52
25/24/15	52
26/15	54/53/52
27/28/15	52

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vanney et al. (6,237,607) discloses an analogous method of delivering an implant between a coronary artery and the left ventricle, however, the implant is not expandable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone


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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 19<sup>th</sup>, 2005

Patricia M Bianco  
Primary Examiner  
Art Unit 3761

  
**PATRICIA BIANCO**  
**PRIMARY EXAMINER**